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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/751,472	12/29/2000	Dinesh Mody	GUID-117	7176

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LAW OFFICE OF ALAN W. CANNON
942 MESA OAK COURT
SUNNYVALE, CA 94086

EXAMINER	
SHAY, DAVID M	
ART UNIT	PAPER NUMBER
3735	
MAIL DATE	DELIVERY MODE
07/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/751,472	MODY ET AL.	
	Examiner	Art Unit	
	david shay	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *April 11, 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5-10, 17, 19, 25, 28, 31, 40, 70-80, 83-86, 89-91, 97, 100-102, 104-107, 225, 229-232, 239-244, 246, 250-255, 282, 284-291, 293-304* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,5-10,17,19,25,28,31,40,70-80,83-86,89-91,97,100-102,104-107,225,229-232,239-244,246,250-255,282,284-291 and 293-304.

The rejections under 35 U.S.C. 112, first paragraph and the rejection based on Roth et al have been withdrawn in view of applicants' comments and amendments, respectively.

With regard to the rejection based on Sinofsky et al, applicants argue that the examiner is relying on the relative scale of the drawing to infer that the optical fiber is oval. The examiner must disagree. It is well settled that "Drawings and pictures can anticipate claims if they clearly show the structure which is claimed." (see In re Mraz, 455 F.2d 1069, 173 USPQ 25 (CCPA 1972)). As it has already been determined "drawings must be evaluated for what they reasonably disclose and suggest to one of ordinary skill in the art" (see In re Aslanian, 590 F.2d 911, 200 USPQ 500 (CCPA 979)). Thus the examiner submits that the oval cross-section of the fiber is clearly shown in the drawing, and thus the oval fiber and passage is "reasonably disclosed and suggested to one of ordinary skill in the art" by the drawing. It is further noted that when "the reference does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value." (see Hockerson-Halberstadt, Inc. v. Avia Group Int 'l, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000)). See MPEP 2125. Thus the examiner is not employing any sort of double standard, arbitrary or otherwise, with respect to the drawings. It is clear that the drawings show the passage and fiber as oval, this is irrespective the particular measurement assigned to any particular element in Figure 2. It is equally clear that applicant's analysis, based on assumed measurements cannot be the basis for a successful argument to distinguish the claims over the applied art.

With regard to Figure 3A, applicant argues that there "does not appear to be any disclosure of causing the light diffusing element to move by moving the optical fiber 18 or of

compressing light diffusion element 32 with optical fiber 18" and requests clarification by the examiner. The examiner respectfully submits that Figure 3A does not illustrate the embodiment of the light applicator wherein the fiber moves. This embodiment is shown in Figure 3B, and discussed at column 3, lines 30-35. As one of ordinary skill in the art would readily understand from the drawing, the fiber 18A is advanced from its original position, shown by the solid line, to the ending position shown by the dotted line. The small gap between the fiber 18A exterior and the interior wall of the housing 26, is clearly for allowing the fiber to move freely within the passage. Again, as one of ordinary skill in the art would easily understand, the gap would be made as small as possible for several reasons: to prevent binding of the fiber as it is advanced, as discussed on the previous office action, which discussion is included herein by reference; to prevent the material of the scattering medium from being pierced by the fiber and occupying the space between the fiber and the housing, where it would then scatter light proximally of the distal end of the fiber, which would defeat the entire purpose of having the fiber be slidably displaceable; and to prevent the exterior of the fiber from being scratched by the alumina, silica and titania compounds and as such be rendered light transmitting, rather than totally internally reflecting.

Lastly, applicant asserts that the light exiting the scattering element of Sinofsky et al "is reflected, by scattering, not emitted" and thus does not read on the claims. The examiner must respectfully note firstly that the originally filed disclosure discloses that "the ablative energy emitted by the energy delivery portion 27 of the ablative device 26 may be one of several types... as will be discussed in greater detail below, the ablative energy may also be derived from a laser source, a cryogenic source, an ultrasonic source or a radiofrequency source, to name a few." (see

the originally filed disclosure, page 29, lines 15-30), thus the instantly described laser embodiment emits laser radiation from the probe. However, the examiner must respectfully note secondly that the laser embodiment of the instant device also "reflects" the light which is "emitted" from the fiber (see the originally filed disclosure, page 40, lines 26-40). Thus, reflected light must be considered to be "emitted" within the meaning of the term as set forth in the specification. Thus this argument is not convincing.

With regard to the rejection based on Sinofsky et al and Bednarek (U. S. Patent No. 5,785,706) under 35 U.S.C. 103(a), applicants argue Sinofsky et al do not teach the maintaining of rotational alignment. As set forth above, this concept is fairly contained within the four corners of the Sinofsky et al reference, and thus this argument is not convincing.

Next applicants question whether or not U. S. Patent No. 5,314,466 is being applied as part of the grounds of rejection. The examiner respectfully submits that it is not necessary to include this reference as part of the rejection, if for no other reason than applicant have chosen to incorporate this patent by reference in the BACKGROUND OF THE INVENTION under the section of "Prior Art". Thus clearly the teachings of this patent are part of the admitted prior art, and thus specific reference to the patent in the rejections is not necessary. The patent teaches directionalized application of energy (as does the Sinofsky et al patent, which additionally teaches the equivalence of directionalized radiation (e.g. in Fig. 2 thereof) and undirectionalized radiation (e.g. in Fig. 4 thereof)). The examiner is merely pointing out that such directionalization is already known to one of ordinary skill in the art with respect to microwave application as well, which should be indisputable, as applicants themselves have discussed a disclosure thereof with respect to the prior art.

Regarding claim 101, applicants infer from the examiner's reasoning that "the provision of a cutout, so that no material exists between the emitter and the tissue, would allow less energy transfer to the tissue than the provision of a dielectric material. This argument suffers several flaws. Firstly, the provision of cutouts is not synonymous with performing the operation in a vacuum (where there would be "no material" existing between the emitter and the tissue. In fact, bodily fluids are notoriously conductive, and thus do not have a "low loss coefficient at microwave frequencies". Further, if no fluid is present, then air, which has a low loss coefficient, will occupy the space. Thus applicants' inference is not correct.

Thus, as Sinofsky et al clearly teach a key assembly which is of the same configuration (i.e. oval) as the key assembly of Figure 20A of the instant application, it will clearly maintain rotational orientation to the same degree as applicants' key structure.

Turning now to the rejections under 35 U.S.C. 103(a), applicants assert that the paragraph of Cox et al noted by the examiner does not teach an pericardial procedure. While the examiner disagrees, there can be no dispute that the disclosure of Cox et al, with regard to the device and method as shown in Figure 21 teaches an epicardial application: ""Figure 21 is an upper left, posterior perspective view of the human heart illustrating the formation of an additional epicardial pulmonary vein isolation cryolesion." (page 10, lines 8-10). Further, with regard to Sinofsky et al, there is disclosed (a cardiac ablation instrument for endo or epicardial ablation of tissue" (see column 1, first paragraph). Thus while neither of these references teach "a procedure for using the device of Bednarek in an epicardial procedure" this is not a requirement for a proper rejection under 35 U.S.C. 103(a), the examiner need only show that it would have ben obvious for one of ordinary skill in the art to do so, in view of the teachings, not that the

references specifically teach the precise combination of references which the examiner is employing. Thus this argument is not convincing.

With regard to the remainder of applicants' arguments, these rely on the recitations of claim 1 to provide patentability, since, as set forth above, claim 1 is not patentable, these arguments are not convincing.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 303 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Bednarek (U. S. Patent No. 5,785,706).

See column 11, line 26 to column 12, line 44.

Claims 107, 225, 240, 243, 246, 253, 293-295, 297, 303, and 304 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sinofsky et al.

See Figures 1-7 and column 1, line 34 to column 4, line 25, the non-circular cross section being illustrated in Figure 2, the insertion of the optical fiber occurring e.g. during the manufacture of the device. It is noted that applicant has amended claim 225 to recite that the at least one sheath is not coaxially aligned with the ablation sheath. While this structure is not per se shown in the Sinofsky et al reference, the claimed structure cannot be used to patentably distinguish over the prior art absent a manipulative effect thereof on the method. Ex Parte Pfeiffer 782 OG 639, 1962 CD 408.

Claims 1, 5, 9, 10, 25, 28, 31, 71, 72, 86, 89-91, 97, 100-102, 106, 296, 298, and 299 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek (U. S. Patent No. 5,785,706) in combination with Sinofsky et al. Bednarek (U. S. Patent No. 5,785,706) teach a

method such as claimed (see Figures 1-8 and column 12, lines 15-29) except the maintaining of rotational alignment. Sinofsky et al teach a cardiac ablation device employing a slidably positionable ablation element with a rotationally asymmetric cross section positioned in sheath in a lumen with a complimentary shape wherein the energy can be directionalized. It would have been obvious to the artisan of ordinary skill to employ the rotationally asymmetric cross section lumen and ablative element of Sinofsky et al in the method of Bednarik et al, since this would enable less energy to be used in the procedure, since more of it would be directed towards the tissue while assuring that the operative direction could be reliably pointed towards the tissue of interest, or to include the various types of ablation energy and the various procedural steps of Bednarik et al in the method of Sinofsky et al, since the various energies are equivalents, as taught by Bednarik et al and Sinofsky et al do not elucidate the procedural steps required to approach the heart intravenously, to employ the jugular vein, since this is a large vessel in the neck, and to configure the ablative element to directionalize the energy or employ an cryosurgical element, since this does not manipulatively affect the method, thus producing a method such as claimed.

Claims 6-8, 17, 19, 40, 70, 78, 79, 104, 105, 225, 229-232, 239-244, 246, 250-255, 282, 284-291, 300, and 301 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek (U. S. Patent No. 5,785,706) in combination with Sinofsky et al as applied to claims 1, 5, 9-11, 14-16, 25-33, 43-54, 58-64, 71, 72, 86, 87, 89-91, 97, 100-105, 296, 298, and 299 above, and further in combination with Cox et al (WO '187) and the admitted prior art of simplifying the procedure, as simplification is desirable; employing a key to enable the surgeon to recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense

the temperature, since this notorious in ablation systems; to sense contact between the device and the tissue to be ablated, since this is notorious for ablating in sensitive organs such as the heart; and to apply energy to assure that the ablation has been effective; and performing a portion of a bypass graft procedure before or after forming one lesion, since bypass procedures are sometimes performed in conjunction with ablation procedures. Cox et al (WO '187) teach the equivalence of laser, ultrasound, microwave, and cryosurgical energies as means of ablation, ablating tissue of the heart through a hole in the chest wall, use of a malleable end which can be pre-shaped; use of a sheath with a cut out window; and various manipulations of the device including ablating around the pulmonary vein, ablating on the epicardium, and positioning the device in three or more positions. It would have been obvious to the artisan of ordinary skill to employ the maze procedure and ablation means of Cox et al (WO '187) in the combined method of Bednarek (U. S. Patent No. 5,785,706) in combination with Sinofsky et al, or to employ the particular ablation steps of the combined teachings of Bednarek (U. S. Patent No. 5,785,706) in combination with Sinofsky et al in the method of Cox et al (WO '187) since Cox et al (WO '187) teach no particular form for the non-cryogenic ablation elements; to employ the various non cryogenic directional ablation element features claimed since these are merely a matter of choice and provides no unexpected result and are known means for providing the desirable functions of Cox et al (WO '187), such as directionality with these equivalent forms of ablation energy discussed by Cox et al (WO '187); to include a cutting member on the distal end of the sheath, since this would allow the cut to be made without introducing an additional tool, thus simplifying the procedure, as simplification is desirable, official notice of which is hereby taken; as well as to position the device adjacent to or in contact with the oblique or transverse sinuses as these are

both structures associated with pulmonary veins and would be contacted in conjunction with the procedure shown in figure 21 of Cox et al (WO '187); to employ a key to enable the surgeon to recognize the orientation of the surgical device, since this is a notorious orientation indicator in the art; to sense the temperature, since this notorious in ablation systems; to sense contact between the device and the tissue to be ablated, since this is notorious for ablating in sensitive organs such as the heart; to apply energy to assure that the ablation has been effective since this is also notorious in the art; official notice of all of these having already been taken and to perform a portion of a bypass graft procedure before or after forming one lesion, since bypass procedures are sometimes performed in conjunction with ablation procedures official notice of which is hereby taken and to form the lumen such that it is not coaxially aligned with the ablation sheath, since this is not critical; is well within the skill of one having ordinary skill in the art; and provides no unexpected result, thus producing a method such as claimed.

Claims 70-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek (U. S. Patent No. 5,785,706) in combination with Sinofsky et al and Cox et al (WO '187) as applied to claims 6-8, 17, 19, 40, 70, 78, 79, 104, 105, 225, 229-232, 239-244, 246, 250-255, 282, 284-291, 300, and 301 above, and further in combination with Swanson et al. Swanson et al teach using temperatures sensors to control ablation and electrodes to pace, map, etc. the heart in a maze procedure wherein the pulmonary vein is encircled. It would have been obvious to the artisan of ordinary skill to employ the sensors and the pulmonary vein encircling device in the combined method of Bednarek (U. S. Patent No. 5,785,706) in combination with Sinofsky et al and Cox et al (WO '187), since this would enable the performance of beneficial cardiac procedures such as maze or to employ the longitudinally translatable ablation element of the

combined method of Bednarek (U. S. Patent No. 5,785,706) in combination with Sinofsky et al and Cox et al (WO '187) in the method of Swanson et al, since this can create longer lesions with a single ablation element, this producing a method such as claimed.

Claims 80, 83-86, and 89-91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek (U. S. Patent No. 5,785,706) in combination with Sinofsky et al and Cox et al (WO '187) as applied to claims 6-8, 17, 19, 40, 70, 78, 79, 104, 105, 225, 229-232, 239-244, 246, 250-255, 282, 284-291, 300, and 301 above, and further in view of Kesten et al. Kesten et al teach delivering ablation devices with a pre-shaped sleeve to reach the ventricles via peripheral veins. It would have been obvious to the artisan of ordinary skills to employ the sheath, delivering route, and treatment region of Kesten et al in the combined method Bednarek (U. S. Patent No. 5,785,706) in combination with Sinofsky et al and Cox et al (WO '187) or to employ the directional slidable probe in a sheath of the combined method of Bednarek (U. S. Patent No. 5,785,706) in combination with Sinofsky et al and Cox et al (WO '187) in the method of Kesten et al, since this would allow the treatment of an elongated area without repositioning the device and in either case to treat one of the atria or ventricles since these chambers are the site of beneficial treatments, official notice of which has already been taken and to employ an alternate access route such as the jugular or subclavian vein, since these are recognized catheter insertion routes in the art, official notice of which has already been taken, thus producing a method such as claimed.

Claim 302 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bednarek (U. S. Patent No. 5,785,706) in combination with Sinofsky et al as applied to claims 1, 5, 9-11, 14-16, 25-33, 43-54, 58-64, 71, 72, 86, 87, 89-91, 97, 100-105, 296, 298, and 299 above, and further in

combination with Kesten et al. Kesten et al teach delivering ablation devices with a pre-shaped sleeve to reach the ventricles via peripheral veins. It would have been obvious to the artisan of ordinary skills to employ the sheath, delivering route, and treatment region of Kesten et al in the combined method Bednarek (U. S. Patent No. 5,785,706) in combination with Sinofsky et al a or to employ the directional slidable probe in a sheath of the combined method of Bednarek (U. S. Patent No. 5,785,706) in combination with Sinofsky et al in the method of Kesten et al, since this would allow the treatment of an elongated area without repositioning the device and in either case to treat one of the atria or ventricles since these chambers are the site of beneficial treatments, official notice of which has already been taken and to employ an alternate access route such as the jugular or subclavian vein, since these are recognized catheter insertion routes in the art, official notice of which has already been taken, thus producing a method such as claimed.

Applicant's arguments filed April 11, 2008 have been fully considered but they are not persuasive. The arguments are not persuasive for the reasons set forth above.

Applicant's arguments with respect to claims 302-304 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3735